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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,165	11/20/2003	Ronald W. Pero	4935-102 US	8978

7590 03/31/2005

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/718,165	Applicant(s) PERO ET AL.	
	Examiner Michele Flood	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 15, 18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 15 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on November 20, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/04; 7/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 15, 2004. Further acknowledgment is made of Applicant's cancellation of Claims 13, 16, 17 and 19.

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-12,14,15 and 18, in the reply filed on September 30, 2004 is acknowledged. Acknowledgment is made of Applicant's request to examine the invention of Group II, that is amended Claim 21, since the claim is now limited to green tea is unpersuasive because the product-by-process of the invention of Group I has been found useful in 14 different methods of treatment, as evidenced by the claims themselves, as set forth in the previous Office action.

Claims 1-12,14,15, and 18 are under examination.

Specification

The disclosure is objected to for the following informality: The heading "DRAWINGS" does not appear between lines 23 and 24 on page 12. Appropriate correction is required.

Claim Objections

Claim 18 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-12, 14, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishihara et al. (*A).

Applicant claims a process for producing a composition of water-soluble phytomedicinal compounds comprising: combining green tea plant material with water, in a ratio of about 1:5 to about 1:50, at a temperature between about 75°C and about 102°C for a period of time to solubilize a substantial portion of thermal aqueous extractable phytocompounds present in the plant material to produce a first extract; and removing substantially all entities having a molecular weight greater than about 10kd from the extract to produce a composition of water-soluble phytomedicinal compounds. Applicant further claims the process according to claim 1, wherein the plant material is

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selected from the group consisting of leaves, bark flowers, roots, stems, and fruit; wherein the plant material is homogenized; wherein the plant material is known to possess medicinal properties; and, wherein the step of removing substantially all entities having a molecular weight greater than about 10kd from the extract is accomplished by means selected from the group consisting of ultra-filtration, chromatography, dialysis, and centrifugation; and, a product-by-process thereof. Applicant further claims the process according to claim 11, wherein the composition is substantially devoid of pigment.

Ishihara teaches a process of making a composition comprising water-soluble phytomedicinal compounds comprising the steps of extracting green tea leaves with water at 30 to 95°C for 0.5 to 7 hours to produce an extract residue (a first extract); concentrating the obtained extract by ultrafiltration membrane with a fractional molecular weight of 3000 to 6000 and then by reverse osmosis membrane; and spraying the obtained extract. In Column 11, lines 51-67, Ishihara teaches obtaining the extract residue by extracting milled tea leaves with a 5 to 20-fold volume of water, and removing the soluble components from the extract. Ishihara further teaches, "Extraction of 10 kg of tea leaves with 50 to 200 kg of water yields 20 to 40 kg of extract residue and 40 to 160 kg of extract of a Brix value of 2 to 10, depending on the amount of water added." In Column 12, line 25 to Column 13, line 22, expressly teaches processes for producing water-soluble phytomedicinal compounds comprising combining green tea leaves with water, in a ratio of plant material to water within a range of about 1:5 to about 1:50.

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The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-12, 14, 15 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Ishihara et al. (*A).

Applicant's claimed invention of Claims 1-8, 10-12, 14, 15 and 18 was set forth above. Applicant further claims the process according to claim 8, wherein the ratio of plant material to water is within a range of about 1:25 to about 1:35, and the temperature is between about 95°C and about 100°C, and the period of time is between about 1 hour and about 6 hours.

The teachings of Ishihara are set forth above. Ishihara teaches the claimed process except for the claim-designated experimental parameters of ratio of plant material to water. However, it would have been obvious to one of ordinary skill in the art to optimize the method of making the composition taught by Ishihara by adjusting ratio of the ingredients used in the method for obtaining phytomedicinal compounds having a molecular weight less than 10 kd from green tea leaves to provide the instantly claimed invention because at the time the invention was made Ishihara teaches the requisite experimental parameters of temperature and period of extraction, the ingredients and

the amount of the ingredients necessary for the production of water-soluble phytomedicinal compounds from green tea plant material. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to optimize the ratio of the ingredients of green tea plant material and water used in the process for producing water-soluble phytomedicinal compounds taught by Ishihara because it would have been merely a matter of judicious selection to provide a result effect variable, given that it is known in the art of herbal extraction that the amounts of plant material to solvent, the type of solvent used in the extraction process of the herbal material, the temperature of the extraction of the herbal material and the extraction period of time are experimental parameters that govern the extraction of desirable water-soluble compounds from plant material, as suggested by Ishihara, in Column 6, line 34 to Column 7, line 22.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 1-6, 10, 14, 15 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by Lunder (*B) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ishihara et al. (A).

Applicant's claimed invention of Claims 1-6, 10, 14, 15 and 18 was set forth above.

Lunder teaches a process for producing a composition of water-soluble phytomedicinal compounds comprising extracting leaves of green tea with water, at a temperature of from about 90°C to 130°C over a period of 10 to 30 minutes, to obtain an aqueous extract comprising extractable phytochemicals present in the plant material; concentrating the aqueous extract to obtain a liquor, and extracting the liquor with dichloromethane to eliminate pigments from the liquor and obtaining an aqueous phase, recovering phytomedicinal compounds (catechins) from the aqueous phase by mixing the aqueous phase with sand to form a paste, which is eluted with acetone to obtain catechins. Lunder further teaches drying the composition.

The claims are drawn to a process for producing a composition of water-soluble phytomedicinal compounds comprising combining green tea plant material with water, in a ratio of about 1:5 to about 1:50, at a temperature between about 75°C and about 102°C for a period of time to solubilize a substantial portion of thermal aqueous extractable phytochemicals present in the plant material to produce a first extract; and removing substantially all entities having a molecular weight greater than about 10kd from the extract to produce a composition of water-soluble phytomedicinal compounds.

Lunder teaches a process of making a composition of water-soluble phytomedicinal compounds comprising infusing green tea leaves in water at a temperature of from 95°C to 130°C over a period of 10 minutes to 30 minutes to obtain a first extract, eliminating pigments from the extract, and recovering phytomedicinal compounds from the extract. Although Lunder teaches the amounts of green tea leaves used in the referenced method to obtain the referenced composition, Lunder is silent to

the volume amount of water used in the referenced process. However, in Column 1, lines 63-66, Lunder expressly teaches, "After extraction, the leaves are separated by centrifugation, and the extract is concentrated to a heavy liquor having a dry matter content of 25 to 30% by conventional methods." Thus, it would appear that the claim-designated ratio ranges of plant material to water are inherent to the process taught by Lunder, as evidenced by the teachings of Ishihara. For instance, Ishihara teaches a process comprising the one and the same experimental parameters of ingredients, temperature range, and period of time for the extraction of phytomedicinal compounds from green tea leaves, as instantly claimed by Applicant and taught by Lunder; and, wherein the ratio of plant material to water was within the claim-designated range of about 1:5 to about 1:50; and, wherein the dry matter content of the first extract comprising water-soluble phytomedicinal compounds from green tea leaf material was the same or essentially the same percentage amount as the dry matter content of the first extract obtained in the process taught by Lunder. For example, in Column 11, lines 63-67, Ishihara teaches that hot water extraction of 10 kg of green tea leaves 50 to 200 kg of water yields 20 to 40 kg of extract residue.

The cited reference discloses a process for producing a composition of water-soluble phytomedicinal compounds comprising extracting green tea leaves in hot water to solubilize a substantial portion of thermal aqueous phytocompounds present therein the plant material to produce a first extract; and, removing substantially all entities having a molecular weight greater than about 10kd from the extract to produce the referenced product-by-process ---- which appears to be identical to the presently

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claimed process for producing a composition of water-soluble phytomedicinal compounds from green tea plant material, since the same ingredients, the same or essentially the same amounts of the same ingredients, the same process steps, and the same or essentially the same experimental parameters of temperature range and period of extraction of the plant material used to produce a first extract are one and the same, as instantly claimed by Applicant; and, therefore, the process taught by Lunder is considered to anticipate the claimed process. With regard to the claimed limitation that the claimed process for producing a water-soluble phytomedicinal compounds encompasses combining green tea plant material with water within a range of about 1:5 to about 1:50, absent evidence to the contrary, it would appear that the referenced process inherently encompasses a process step wherein the ratio of plant material to water is one and the ratio of ingredients as instantly claimed, given the teachings of Lunder and Ishihara as set forth above.

In the alternative, even if the claimed process is not identical to the referenced process with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced process is likely to inherently possess the same characteristics of the claimed process particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed process for producing a composition of water-soluble comprising the claim-designated process steps would have been obvious to those of ordinary skill in the art within the meaning of USC 103. For instance, it is not clear from the teachings of Lunder as to the ratio of plant material to water used in the

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process of step of extracting water-soluble phytomedicinal compounds by hot water extraction. However, it would have been obvious to one of ordinary skill in the art to employ the instantly claimed ratio of plant material to water in the making of a composition comprising water-soluble phytomedicinal compounds that are obtained in a hot water extraction of green tea plant material to provide the instantly claimed invention because the adjustment of the weight amount of plant material to the volume amount of a water solvent would have been no more than a matter of judicious selection and optimization to provide a result-effect variable in the extraction of chemical constituents from a plant material known in the art to possess beneficial medicinal properties. Thus, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to adjust the weight amounts of the plant material and the volume amounts of the water used in the process of making the product-by-process taught by Lunder, wherein the ratio of plant material to water was within the claim-designated range of about 1:5 to about 1:50, because at the time the invention was made the claim-designated ratio range was known in the art as being beneficial in the hot water extraction of water-soluble phytomedicinal compounds from green tea plant material, as evidenced by the teachings of Ishihara. For example, Ishihara expressly teaches processes for producing water-soluble phytomedicinal compounds comprising combining green tea leaves with water, in a ratio of plant material to water within a range of about 1:5 to about 1:50, in Column 12, line 25 to Column 13, line 22.

Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to adjust the amounts of the ingredients used in the process taught by Lunder by employing the instantly claimed ratio of plant material to water because it would have been well in the purview of one of ordinary skill in the art practicing the invention to provide the claimed invention, since Lunder teaches the plant material, the extraction solvent of water, the process steps, and the experimental parameters of temperature range and period ranges of time for the extraction for the extraction of water-soluble phytomedicinal compounds from green tea leaves. Hence, the claimed invention is no more than the routine optimization of a result effect variable. Thus, the claimed process would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

The United States Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicant's claimed process and/or product-by-process thereof differs and, if so, to what extent, from that discussed in the references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to Applicant.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Examiner
Art Unit 1654

MCF
March 17, 2005